User's Manual

SPENCER 202
Electronic pulmonary ventilator

CE 0123

This appliance conforms with the Directive 93/42/CEE "Medical Devices".

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH.

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Thank you for choosing a Spencer product

1 GENERAL INFORMATION

1.1 AIM AND CONTENTS

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 CONSERVATION OF THE INSTRUCTION MANUAL

The instruction and maintenance manual must be kept with the product, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 SYMBOLS USED

SYMBOL	MEANING
	General or specific warning
	See instructions for use
SN	Serial number
REF	Product code
CE 0123	The product is compliant with the specifications of the Directive 93/42/CEE
	Type B device
	Keep in a cool and dry place
	Functioning temperature
T\ 1A	Fuse
	Storage temperature
	Battery
	Device with isolation class II
	Information to the users in compliancy with comma 13 of the Italian Legislative Decree n. 151 of 25 July 2005, "Fulfilment of the Directives 2002/95/CE, 2002/96/CE and 2003/108/CE, regarding Reduction of the use of dangerous substances in electric and electronic equipments and the disposal of their wastes"
	Information for end user as indicated in Art. 22 of the Law Decree n. 188 20/11/08 regarding the "implementation of the Directive 2006/66/CE regarding batteries, accumulators and their disposal which annuls the Directive 91/157/CEE"
IP22	Grade of protection IP22
EMC	Electromagnetic compatibility

1.4 SERVICING REQUESTS

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on tel. 0039 0521 541111, fax 0039 0521 541222, e-mail info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY.

1.5 DEMOLITION

Follow the current regulations.

Information to the users in compliancy with comma 13 of the Italian Legislative Decree n. 151 of 25 July 2005, "Fulfilment of the Directives 2002/95/CE, 2002/96/CE and 2003/108/CE, regarding Reduction of the use of dangerous substances in electric and electronic equipments and the disposal of their wastes.

The crossed dustbin symbol applied on the product or on it's packaging indicates that the item should be disposed of separately. The correct disposal of the item when use has terminated, is defined and organised by the manufacturer. The end user who has to proceed with disposal, must therefore contact the manufacturer and follow the system and procedures the manufacturer has organised for the separate collection, treatment and disposal at end-of-life. The correct separate collection of the out of use device which will permit recycling, treatment and destruction in an ecologically friendly manner and will contribute to avoiding possible negative effects on the environment and for health while privileging the reuse and/or recycling of the collected waste components.

Please note that the owner will be subject to administrative sanctions in case of unauthorised disposal of the item.

Information for end user as indicated in Art. 22 of the Law Decree n. 188 20/11/08 regarding the "implementation of the Directive 2006/66/CE regarding batteries, accumulators and their disposal which annuls the Directive 91/157/CEE"

DISPOSAL OF WASTE BATTERIES

This symbol on the battery or on the packaging indicates that the battery provided with this product shall not be treated as household waste. By ensuring these batteries are disposed of correctly, you will help prevent potentially negative consequences for the environment and human health which could otherwise be caused by inappropriate waste handling of the battery. The recycling of the materials will help to conserve natural resources. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, your household waste disposal service or the shop where you purchased the product.

1.6 LABELLING

The serial number as indicated below can be found on each appliance and must not be removed or covered. In order to facilitate assistance please indicate or communicate the serial number (SN) on the label.

Lateral panel

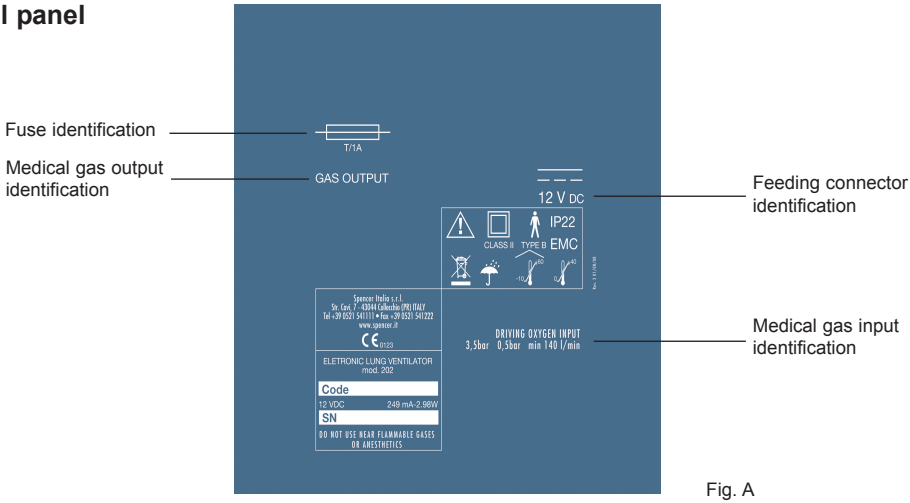


Fig. A

Rear panel

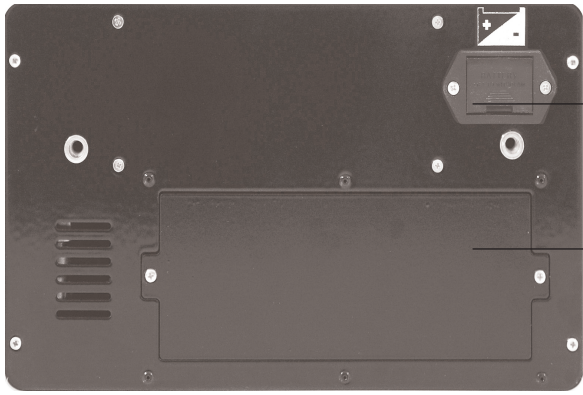


Fig. B

2 WARNINGS

2.1 GENERAL WARNING

- Before carrying out any kind of operation on the appliance, the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Regularly check the appliance.
- In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning and the safety, the appliance must be immediately removed from service.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with. In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself.
- Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Handle with care.

2.2 SPECIFIC WARNINGS

- The product must be used by trained personnel only.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption. If another lung ventilator is not available, ventilation must be immediately re-established manually (ex. Spencer B-life manual resuscitation bag) in order to maintain vital life support. If necessary they can be used with a PEEP valve and reservoir bag for the enrichment with oxygen.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- The device has seals. If they have been removed or tampered with the manufacturer declines any responsibility for the product and for its correct functioning and for any consequent damage that may occur to the device.
- Before turning on the pulmonary ventilator, the battery must be put under charge for at least 12 hours.
- The use of the device with power source and environmental conditions different from those indicated compromises the safety of operating. In the following table are some of the abnormalities that could occur under these conditions:

CONDITIONS	POSSIBLE PROBLEM
Excessive power feeding current	The fuse burns
Low power feeding current	The battery does not recharge
Excessive environmental temperature	• Problems with the sealing membranes • Gas leaks • Excursions of the set flow
Low environmental temperature	Possible presence of condensation (occurring when the ventilator is returned to a higher temperature)

- **The device must be used in a ventilated environment.**
- **A minimum of charge must always be maintained in the battery.**

2.3 CONTRAINDICATIONS AND SIDE EFFECTS

- Do not use the SPENCER 202 pulmonary ventilator in neonatal clinics (0-18 months) and in patients with un drained pneumothorax.
- Do not use the device in presence of inflammable or anaesthetic gases.
- Do not use the device if it is connected to an SPS charger or other transformer 220 V/12 V.
- To avoid hypercapmia effects do not use 100% oxygen for protracted ventilation (the device is provided with a special mixer switch to select mixed oxygen/air at 60% or 100%).

2.4 SAFETY SYSTEMS

The device is provided with the following safety systems:

- **Mechanical overpressure safety valve**
  The maximum limit of device pressure is 60 mbar.
  This value is imposed by the manufacturer. The user can reach the maximum level by use of the regulation knob.
- **Spontaneous breathing**
  When the pulmonary ventilator is off or gas or electrical supply is interrupted, the patient can breathe spontaneously. The device is provided with an independent power supply alarm (9 V battery). This acoustic and visible alarm signals the low battery condition. This alarm functions even if the device is turned off with the switch in the "O" position. The device is provided with an acoustic alarm which functions when the machine is turned on, if the incoming medical gas input is interrupted.

3 DESCRIPTION OF PRODUCT

3.1 INTENDED USE

SPENCER 202 is a breathing control/assistance device, which comprehends the emerging trends in the field of automatic respirators. It is a volumetric type device with electrical control of the respiratory functions, capable of supplying medical gas at two different concentrations with a single gas source, complete with mechanical and electronic safety devices which supervise over some of the principal respiratory parameters. The SPENCER 202 pulmonary ventilator is portable with a two-hour self-powered electric energy system: after two hours external power feeding is necessary, this will automatically recharge the internal system. SPENCER 202 has two operating modes, automatically changed by the software, and a series of warning lights connected to an audible signal which permits rapid identification of any dysfunctions. The user interface is in the front control panel made in a material which is scratch proof and resistant to common medical substances The front panel has clear and intuitive graphics and the operating buttons are protected to avoid accidental functioning. On the right hand side there is a flange with connections for the pressurised oxygen and the supply of medical mix for the patient. The wide range of volumes and respiratory frequencies of the SPENCER 202 and the monitoring system for patient safety permits its use for both adult and paediatric patients.

The device can carry out the following functions:

- Substitute the breathing functions in those patients, who do not breathe spontaneously (controlled ventilation).
- Assist those patients whose breathing functions are irregularly altered and anyway insufficient (automatic breathing system).

The switch from one mode to another is automatically managed by the microprocessor under certain conditions. The following list shows the optimal ventilation parameters:

PATIENT	RESPIRATORY FREQUENCY (RF)	TIDAL VOLUME (TV)	MINUTE VOLUME (MV)
Adult	10-20 breaths/min	10-12 ml/kg	TV x RF
Child up to 15 kg	40 breaths/min	10-15 ml/kg	TV x RF
Child over 15 kg	30-35 breaths/min	10-15 ml/kg	TV x RF

The device has been designed for use on road ambulances.

3.2 MAIN COMPONENTS

The main functional components of the device are the following:

- **Front control panel**
  All the commands and functional selectors are positioned here. Manufactured in anti scratch polycarbonate.
- **Electronic control board**
  Operates the integrated control of all respiratory functions and of the main parameters of respiration.
- **Electro-pneumatic circuit for gas mixing and erogation**
  The pressurised gas in entry is sent to the mixing block thanks to a flow cutting valve that is electronically controlled.
- **Patient circuit**
  It is made up of a corrugated PVC tube, Spencer Mask size 4 face mask, autoclavable non-rebreathing valve in polycarbonate, straight connector and anti batteric filter.

- **100 cm Oxygen connecting tube**
  For connection of the lung ventilator to a source of oxygen.
- **12 V Connecting cable**
  It can be connected to the cigarette lighter socket for the 12V source or to a transformer with the following characteristics:

- inlet source 220/230 Vac 50/60Hz
- outlet 4 V 0,8 Ampere

3.3 MODELS

EV01202A Spencer 202 Electronic pulmonary ventilator
EV02202A Kompak 202 Resuscitation system
EV60202A Porta Vent 202 Rucksack version of resuscitation system

3.4 TECHNICAL DATA

DIMENSIONS	
Width	330 mm
Height	180 mm
Depth	175 mm
Weight (accessories included)	3,5 kg
TECHNICAL CHARACTERISTICS	
Isolation	class II
Grade of protection	IP22
ELECTRIC VALUES	
Electric source	connection to external tension stabilised at 12 Vdc
Charging tension	maximum 14 V
Absorption of current	maximum 249 mA
Absorption of current at 12 Vdc	2.98 W
FUSES	
External powered 12 V	1A
INTERNAL BATTERY (must never be completely flat!)	
Functioning time (average)	2 h
Recharging time	12 h
Functioning time after signalling of low battery	5 min
Internal volume of the patient circuit tubes	351 cm^3
MEDICAL GAS (OXYGEN)	
Input pressure (central system or tank with pressure regulator)	3,5 bar ± 0,5 bar
Minimum capacity	140 L/min
VENTILATION	
Minute volume	from 2 to 20 L/min
Volume delivered (measurable)	(volume/minutes):frequency
Ventilation Frequency	from 5 to 40 BpM
Oxygen concentration	60% or 100%
I:E Ratio	1/2
Pressure (sub-atmospheric) negative in the exhaling phase	Not available
MANOVACCUUMETER	
Tolerance	da -20 a +70 mbar
Range from -20 to +10 mbar	2 mbar
Range from +10 to +70 mbar	5 mbar
MAXIMUM DEVIATION OF SET VALUES	
Medical gas flow	± 15%
Frequency	± 1 BpM

Note:
The medical gas flow is not influenced by pressure. The ventilator does not monitor the oxygen concentration (mechanical mixing). Unless otherwise specified the parameters are expressed in ATPD (Ambient, Temperature and Pressure Dry).

3.5 ENVIRONMENTAL CONDITIONS

	STORAGE AND TRANSPORT	FUNCTIONING
Environmental temperature	from -10 to +60 °C	from 0 to +40 °C
Relative humidity	from 10 to 100%	from 15 to 95%
Atmosferic pressure	from 50 to 106 kPa	from 70 to 110 kPa

3.6 ELECTROMAGNETIC ENVIRONMENT

The SPENCER 202 pulmonary ventilator is created to operate correctly in an electromagnetic environment. It has successfully passed all the electromagnetic tests stipulated in Harmonised Standards by the Notifying Body (see Declaration of Conformity).

3.7 STANDARDS APPLIED

- EN 60601-1+ A1 + A2 + A12 +A13 + corrigenda (July 1994)
- IEC 601-1-2 (EN 60601-1-2)
- EN 794-3
- 89/336/CEE
- 92/31/CEE

3.8 PNEUMATIC DRAWING

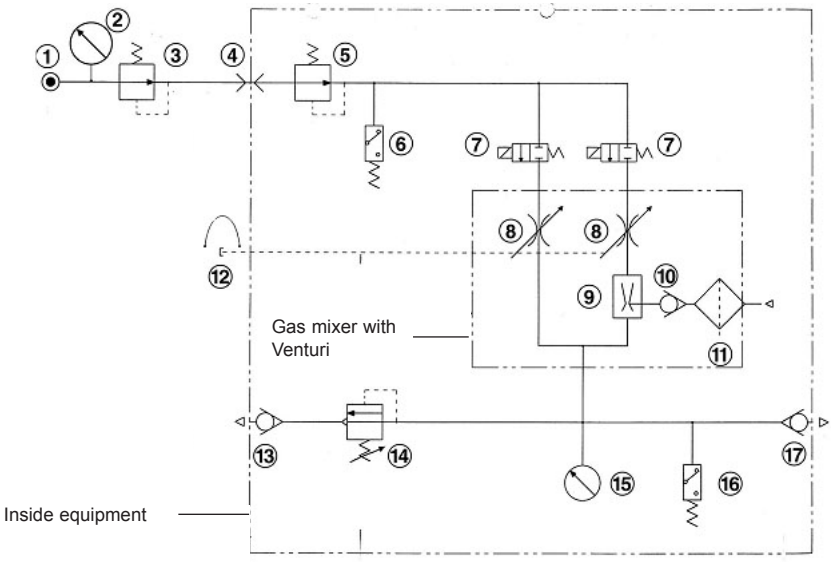


Fig. C

1. High pressure source
2. High pressure gauge
3. High pressure adapter
4. Quick coupling input
5. Low pressure adapter
6. Pressure switch
7. Electrovalve with 2 N.C. outputs
8. Flow regulator with fixed capacity
9. Venturi system
10. No-return valve
11. Aspiration air filter
12. Capacity selection knob
13. Overpressure release with no-return valve
14. Overpressure release valve
15. Low pressure erogation manometer
16. Pressure switch
17. Outlet with no-return valve

4 OPERATING INSTRUCTIONS

4.1 TRANSPORT AND STORAGE

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks, bumps or falls during the transport itself.

Keep the original packaging for use in case of any further transport. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The appliance must be stored in a dry place free from humidity.

In case of prolonged periods of inactivity or before transportation:

1. Switch is in off position "O".
2. Unplug the power lead.
3. Check the charge status of the internal battery and re-charge it, if necessary.

In case of long inactivity, in addition to these recommendations, the device must be stored with the precautions relevant to the place and time of stocking:

- Store the pulmonary ventilator in a closed place.

- Keep it from stress and impacts.
- Protect it from humidity as well as excessive thermal excursions.
- Avoid contact with corrosive substances.

4.2 PREPARATION

On receipt of the product:

- Remove the packaging and display the material so that all components are visible.
- Check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.

- Put the pulmonary ventilator on a flat surface (i.e. shelf, trolley).
- If used on an ambulance, the device must be fixed correctly, using the purpose made threaded holes, with diameter 6 threaded screws.
- It is possible to fix the pulmonary ventilator on a rail with the purpose made hooks.

The operations of preparation listed below must be carried out and checked before every use.

	To check	Result required
RESPIRATORY SYSTEM	• Corrugated tube • Non-rebreathing valve • Overpressure test • Face mask • Ventilation test • Anti batteric filter • Straight connector	• All components must be intact and correctly connected • See paragraph 4.5.2 "Operating instructions"
ELECTRIC POWER SUPPLY	• Press on switch "I"	• The respirator ventilates

Ensure the availability of a mechanical/manual ventilation system (i.e. resuscitation bag Spencer B-life). Before using the device check the correct functioning of the alarm LED by applying pressure (at least 2 sec) on the acoustic turnoff button. During the test the LED lights up and the buzzer will sound.

The device must be used in a ventilated environment.

4.3 ELECTRIC SOURCE

4.3.1 Control of alarms battery 9 V

The 9 V alarms battery should be regularly checked or replaced depending on its use. Through digital tester, verify that the voltage of the 9 V battery is not lower than 10%. The correct polarity for the reintegration of the 9 V battery is guaranteed by the seat of the battery holder and symbols indicated. For older versions Kompak and Porta Vent exercise care and reassemble the fan frame without excessive force on the rear M6 allen.

4.3.2 First charge of the internal battery

The SPENCER 202 pulmonary ventilator is powered by a rechargeable battery. A new battery is never completely charged. It will be charged completely only if left under charge it for 24 hours non stop before first use. The battery, recharges automatically during normal functioning of the device connected to the 12 Vdc source or with 220 V transformer.

With a fully charged battery in good condition, the ventilator can function for about two hours. With low batteries or battery in bad condition it may function for a shorter time.

If the device remains unused for over 3 months, the battery must be recharged. The device must not be left under charging for more than the time indicated. If the battery is allowed to become flat and/or if the device is left attached to the source the life of the battery will be considerably reduced.

4.3.3 External 12 Vdc source

An external source may be used in emergency situations or during the use of the ventilator on ambulances and/or helicopters. Use only electric connection cable code EV20010A. The free end of the cable must be correctly connected with the direct current plug.

Connection specifications	
Red or brown wire	on + (positive pole)
White wire	on - (negative pole)
Shielding	on - (negative pole)

Insert the connector on the ventilator side.

The device indicates the connection with the net through the "Ext. source" LED.

4.3.4 Emergency electrical feeding through a supplementary battery

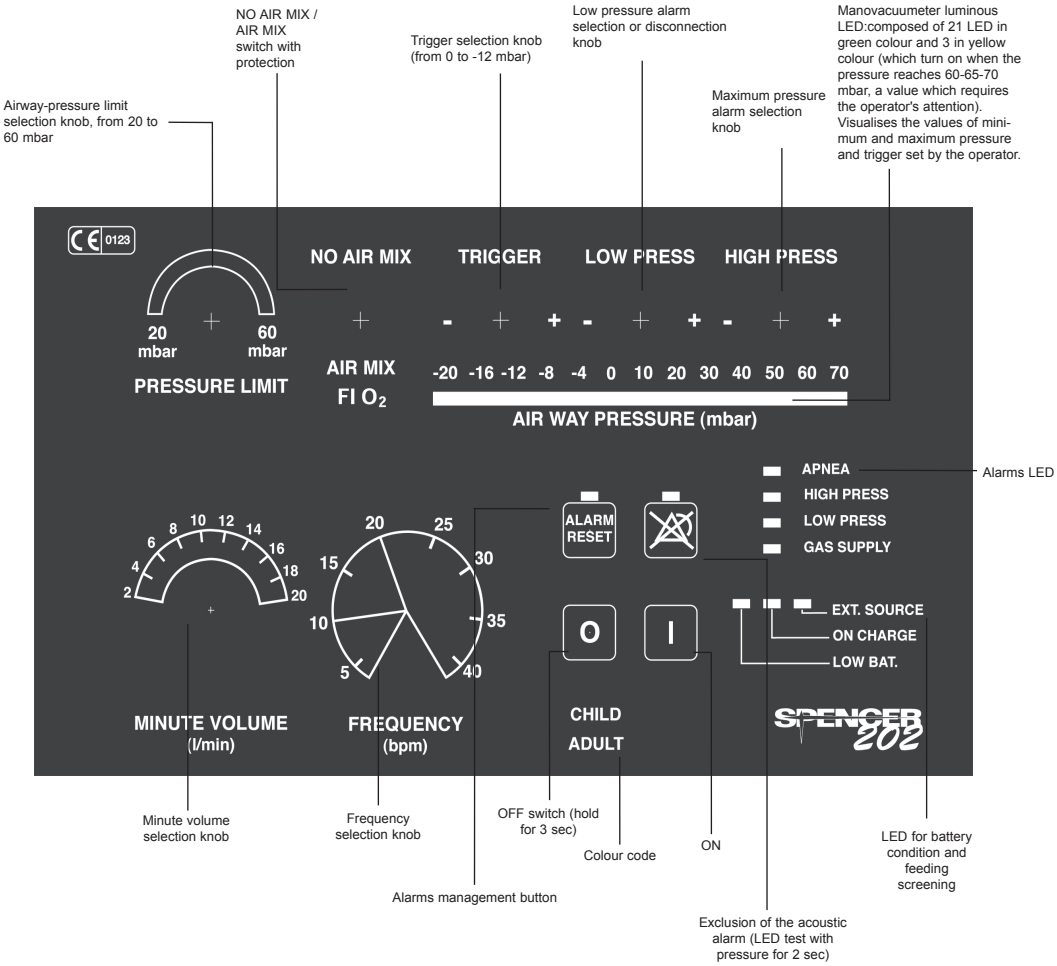
Do not put the spare battery on the device. It must be placed as far as possible from the inlet air filter of the ventilator.

4.4 FEEDING COMPRESSED GAS

Use oxygen (central system or oxygen tank with pressure regulator) or compressed medical air with an entrance pressure from 3,5 bar ± 0,5 bar and a minimum capacity of 140 L/min.

4.5 FUNCTIONING
4.5.1 Front control panel

Fig. D


NO AIR MIX / AIR MIX switch with protection
Trigger selection knob (from 0 to -12 mbar)
Low pressure alarm selection or disconnection knob
Manovacuumeter luminous LED:composed of 21 LED in green colour and 3 in yellow colour (which turn on when the pressure reaches 60-65-70 mbar, a value which requires the operator's attention). Visualises the values of minimum and maximum pressure and trigger set by the operator.
Airway-pressure limit selection knob, from 20 to 60 mbar
Maximum pressure alarm selection knob
NO AIR MIX
TRIGGER
LOW PRESS
HIGH PRESS
20 mbar
60 mbar
PRESSURE LIMIT
AIR MIX
FI O2
-20 -16 -12 -8 -4 0 10 20 30 40 50 60 70
AIR WAY PRESSURE (mbar)
APNEA
HIGH PRESS
LOW PRESS
GAS SUPPLY
Alarms LED
ALARM RESET
EXT. SOURCE
ON CHARGE
LOW BAT.
MINUTE VOLUME (l/min)
FREQUENCY (bpm)
CHILD
ADULT
SPENCER 202
Minute volume selection knob
Frequency selection knob
OFF switch (hold for 3 sec)
Colour code
ON
LED for battery condition and feeding screening
Alarms management button
Exclusion of the acoustic alarm (LED test with pressure for 2 sec)

4.5.2 Operating instructions

When turning on the device, the microprocessor automatically switches the ventilator to the default "controlled" mode and checks the acoustic alarm inhibiting it for about 30 seconds detailing any information on the front panel in the dedicated alarm section. Erogation of medical gas to the patient starts in cycles at regular intervals in correspondence with the relevant frequency selected by the command. The current volume of mix sent to each breathing act is detected in the following way: read the set value on the "minute volume" button and divide it by the set "frequency".

The real pressure of the patient circuit is always monitored by the luminous manovacuumeter on the front panel. For the duration of functioning, the microprocessor regulates the cyclical erogation of medical gas and verifies the state of some parameters of breathing, moreover it signals the exceeding of safety limits activating, depending on the case, the acoustic and/or luminous signals. The different functioning modes are described in the next paragraph 5.3 "Functioning modes".

Apnoea will be detected by the device only if the patient after one or more spontaneous inspirations (situation which automatically activates the "assisted" functional mode), interrupts breathing during the breathing cycle (8 seconds). In this case the lung ventilator activates the luminous/acoustic signal of apnoea and commutes automatically in "controlled" (erogated mix at fixed frequency), it turns on the luminous signal of apnoea. Should the patient start to breathe naturally the device will automatically go back to "assisted/controlled" mode and cancel any alarm signals, which are still active.

It is essential to regulate first the ventilator volume and then pressure because if the volume was to be regulated after the pressure it would cause an immediate change of the pressure limit. After choosing volume ventilation, use the palm of the hand to keep the outlet of the patient valve (where the mask normally is attached) and then regulate the pressure limit with the knob.
Hyperextend the head and check the passage of the air by inserting an oral-pharynx cannula (or Guedel cannula) in the patient's mouth with the usual manoeuvre. Place the ventilation mask on the mouth and on the nose of the patient checking the adhesion of the soft part of the mask on the patient's face for a tight fitting. Selection method of the minute volume knob (step selector) prevents undesired value changing during functioning in case of accidental touch.
If the patient is intubated, remove the ventilation mask of the patient valve. Insert the free adapter the endotracheal tube with its own connector. Resistance of the patient airways due to obstructions or to external cardiac massage do not involve a frequency and respiratory volume modification. In case of lung compliance reduction, the ventilator reacts with an increase of the respiratory pressure at a constant volume.
When use of the SPENCER 202 terminates it is necessary to:

- Press the off button "O" (for 2 seconds)
- Interrupt oxygen supply by closing the valve on the oxygen tank or by disconnecting the oxygen tube connection

4.5.3 Functioning modes

- **Assisted/controlled ventilation**

Start halfway through the exhaling phase it extends for the duration of the whole exhaling phase. Any attempt of the patient to inhale sufficient amounts of product in this interval determines the start of a new breathing act and the consequent delivery of medical gas flow. Attempts to inspire made outside this interval are not accepted: anticipated attempts because they could be caused by transitional situations in the patient circuit and could simulate voluntary breathing; late attempts as they could not show, since the machine switches automatically to controlled mode if the maximum limiter of wait is exceeded, thus inhibiting any attempt to inhale except for the final part of the exhaling phase.
In case of exceeded maximum pause period, the apnoea situation is signalled visually and acoustically. The alarm remains active until acceptance on the part of the respirator of an attempted inhalation valid as from the patient or until the alarm cancelling button "Reset alarms" is pressed.
This functioning mode guarantees prompt intervention of the machine in case spontaneous breathing of the patient stops but also allows for an easy adaptation of the patient as it permits variations in the breathing frequency of up to 50% increase or decrease.
It is important though that the breathing frequency selected is as close as possible to the natural breathing of the patient. The intervention of the apnoea alarm means that the selected frequency is too high and the patient cannot maintain the rhythm of the device.

- **Assisted ventilation (IPPV with trigger)**

This function ensures that flowing volumes are of fixed duration and they are erogated to the patient. These volumes can be set by means of the frequency knob and of the minute volume intervals, following the patient's natural breathing rhythm.The inhaling and exhaling ratio depend on the characteristics of the patient's natural breathing, however can be corrected using the frequency knob, which in this circumstance determines the duration of the inhaling phase only,
The duration of the inhaling phase is calculated dividing by 3 the duration of the whole breathing act.

E.g..:	Frequency	F = 10 breaths/min
	Inhalation	INS = 60 / 3 * F = 2 sec
	F = 5	INS = 60 / 3 * 5 = 4 sec
	F = 20	INS = 60 / 3 * 20 = 1 sec

The flow volume erogated by the patient at each inhalation is calculated dividing the volume/minute, set on the knob positioned bottom right of the front panel, by the number of acts per minute set on the frequency knob.

- **Trigger**

The trigger is a special device able to synchronise the insufflation with the beginning of spontaneous inhalation of the patient. The ventilation supporting technique is normally employed on patients who are able to sustain inhalation work at brief intervals.
The patient's effort to produce spontaneous breathing generates inside the respirator a negative pressure which triggers rapidly the insufflation, thank to the trigger mechanism.
The effort (or negative pressure) necessary to set off the trigger mechanism can be regulated and increased progressively in order to aid and prompt the patient towards breathing spontaneously, re-educating and training the breathing muscles. The range of regulation goes from 0 to - 12 mbar.

4.5.4 Alarms

Any alarm signal corresponds to an abnormal functioning condition, which demands the intervention of the operator. Following are the various abnormal situations which may determine the activation of alarms with the relevant corrective actions the operator must carry out to resolve them.

- **Maximum pressure (selected by user)**

Signal: visual and acoustic with the interruption of the medical gas
Meaning: exceeded superior safety limit of the patient circuit pressure
Cause 1: the minute volume selected is too high
Correction 1: decrease the minute volume selected
Cause 2: the connection tube is squashed
Correction 2: free the connection and put it in a safe condition
Cause 3: the minute volume selected is correct but the internal resistance of the patient in certain conditions may cause intervention of an alarm
Correction 3: position the pressure limiter at a lower level so that the patient circuit can be discharged without alarm intervention
Cause 4: the pressure limiter does not work correctly
Correction 4: send the device back to the manufacturer for a maintenance check

- **Minimum pressure (selected by user)**
  Signal: visual and acoustic
  Meaning: the pressure in the patient circuit does not reach the minimum value expected during the inhalation phase
  Cause 1: the patient circuit is not connected to the patient
  Correction 1: re-effect the connection
  Cause 2: there is no medical gas
  Correction 2: check that the medical gas alarm is not on, verify the connection with the power source, verify the condition of the power source
  Cause 3: the minute volume selected is insufficient: the patient manifests a breathing rate superior to the machine erogation
  Correction 3: adapt the minute volume to the patient's needs
- **Software fault**
  Signal: intermittent visual (all LEDs on) and acoustic
  Meaning:
  - an error in the execution of the software program occurred
  - a RAM fault occurred
  - general malfunctioning of the microprocessor occurred
  Correction: send the lung ventilator back to the manufacturer
- **Apnoea**
  Signal: visual and acoustic
  Meaning: the device did not automatically wait for voluntary inhalation of the patient
  Cause 1: the connection between patient and device was interrupted
  Correction 1: re-effect the connection
  Cause 2: the patient stopped breathing spontaneously
  Correction 2: verify that controlled breathing is automatic
- **Battery**
  Signal: intermittent visual and acoustic
  Meaning: the internal battery needs recharging
  Correction: connect the ventilator to an external feeding source in compliance with the specifications provided in paragraph 4.3 "Electric Source"
- **Medical gas**
  Signal: visual and acoustic
  Meaning: the source of medical gas has insufficient pressure and/or capacity
  Correction: verify the line and source of feeding

Alarm inhibition
On the front panel, on the dedicated alarm section, there are two buttons (reset alarms and acoustic exclusion) which inhibit the alarm signals. Reset alarms cancels any selected alarms and must be activated once the cause for the alarm has been removed, in order to avoid that the signal remains active.
Acoustic excluded inhibits for about one minute, thirty seconds the acoustic signal in order to permit corrective interventions in better conditions. The signal of discharged battery and the absence of medical gas are not influenced by the activation of the above commands. The relevant signals are turned off only when the cause, which activated them, is removed. The apnoea alarm can be removed, not only by activating the reset alarms and acoustic exclusion buttons, but also from the moment the patient starts spontaneously breathing again.

4.6 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
Gas supply alarm	The ventilator is not connected to a compressed gas source (oxygen or medical gas)	Connect the ventilator to a medical gas supplying source
	The oxygen bottle is empty	Replace with another bottle that is full and fill the empty one
	The pressure or the erogation capacity are not correct (lower than 2,5 bar)	Check the adapter performance
The patient cannot exhale	Patient valve is not in correct position or is damaged	Check the fixing of the valve or replace it
Minimum pressure alarm	Corrugated tube not connected or connected badly	Connect the corrugated tube adequately
	Corrugated tube faulty or not sealed properly	Replace the corrugated tube
Low Paw (pressure of the airways)	The non-rebreathing valve is not adequately connected (after sterilisation) to the tube and/or mask compromising good holding	Adequately connect the non-rebreathing valve to the mask and corrugated tube
	Inferior alarm limiter lower than PEEP	Set to 5 mbar under the maximum pressure of the airways

PROBLEM	CAUSE	REMEDY
Maximum pressure alarm	Obstructed airways	Remove dentures: effect bronco aspiration/suction
	Bent corrugated tube	Ensure that there are no bending or obstructions
	The patient is not hyperextended	Hyperextend or position the Guedel or Berman cannula
	Superior alarm limiter set to a value that is too high	Set to 10 mbar above the maximum value of the airways pressure
Battery is flat	The internal battery has less than 5 minutes of autonomy left	Use an external battery or connect to electricity power; recharge the internal battery immediately (see par. 4.3.2)

5 MAINTENANCE AND CLEANING

5.1 CLEANING

The operations below described must be executed after each use of the SPENCER 202.

- Switch off the pulmonary ventilator
- Isolate it from the power source/net (if connected)
- Disassemble the non-rebreathing valve
- Disassemble the PEEP valve (if present)
- Autoclave the mask and substitute the patient circuit (supplied with antibacterial filter)

On request a re-usable (autoclavable) patient circuit can be provided.

After operating the necessary operations of cleaning/sterilisation the non-rebreathing and PEEP valve (if present) must be reassembled, reconnect the device to power (if necessary).

The external cleaning of the device should be carried out ensuring compatibility of the constructions materials with appropriate surfaces disinfectants as indicated in the table below:

PRODUCTS WHICH CAN BE USED	PRODUCTS WHICH CANNOT BE USED
Disinfecting with aldehydes	Compounds releasing halogens
Disinfecting with alcohol	Strong organic acids
Quaternary ammonia compounds	Compounds releasing oxygen
	Trichloroethylene

5.2 MAINTENANCE

5.2.1 Precautionary Maintenance

The person responsible for every day maintenance can only substitute the spare parts indicated on paragraph 6.2 "Spare Parts". All other substitutions or repairs can be carried out only by the manufacturer or by a centre authorised by the manufacturer.

The device must be serviced by the manufacturer or by an authorised centre every year.

For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

5.2.2 Special servicing

Only the manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

The device, if used as indicated in the following instruction manual, has an average life span of 5 years. The life span can be expanded only following a general revision of the product that must be carried out by the manufacturer or by a centre authorised by the manufacturer.

6 ACCESSORIES AND SPARE PARTS

6.1 ACCESSORIES

EV60030C	EVX 30 PEEP valve autoclavable
EV60032C	EVX 32 PEEP valve disposable
EV20008A	Electric connection cable 150 cm
EV20009A	Electric connection cable 250 cm
EV20010A	Electric connection cable 40 cm
EV20011A	Electric connection cable 200 cm

6.2 SPARE PARTS

EV00106A	Patient circuit complete with antibacterial filter
EV50020A	Patient circuit tube in PVC, diameter 22x120 cm
EV50021A	Straight connection 22 M / 15 F for patient circuit
EV50011K	Non-rebreathing valve in polycarbonate
EV50025E	Patient circuit tube in silicone, diameter 22x120 cm
EV50110K	Disposable resuscitation filter, latex free
OX08000A	Fuse 1 Ampere
EV30090E	Alkaline battery 9 V "PP3"
OX07005A	Tube connector, diameter 7 M 1/8
OX07006A	Cylindrical tube connector, diameter 7 M 1/4 G
OX05013A	Outlet for oxygen connection UNI 9507
OX90007A	Ring clamp 11-13

Warning
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